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10/025,137	12/19/2001	Lu-Yieng Liu	12674-005001	4889

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EXAMINER
SITTON, JEHANNE SOUAYA

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,137	LIU ET AL.	
	Examiner	Art Unit	
	Jehanne Souaya Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 23-43* is/are pending in the application.

4a) Of the above claim(s) *27-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 23-26, and 36-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-15, and 23-43 are pending in the instant application. Claims 27-35 have been withdrawn from consideration as being drawn to a nonelected invention. Claims 36-43 are newly added. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented, as necessitated by amendment, or are reiterated from the previous office action. They represent the complete being presently applied to the instantly examined claims. Response to arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The objection to the specification made in section 4 of the previous office action is withdrawn in view of the amendments to the sequence listing and the verified statement that the newly added sequence was the version of nt 81889-93238 from Genbank Accession number AP002562 at the time the instant application was filed.

4. The objection made to claims 9 and 12 is withdrawn in view of applicants arguments at page 8 of the response.

5. The rejection made to claims 1-4 and 8-11made under 35 USC 112/first paragraph under written description, in section 7 of the previous office action, is withdrawn in view of the

amendments to the sequence listing and the verified statement that the newly added sequence was the version of nt 81889-93238 from Genbank Accession number AP002562 at the time the instant application was filed.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

6. Claims 8-14 and newly added claims 36-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims reciting nucleic acid sets containing probes that comprise SEQ ID NOS 5-8 and are anywhere from 200 up to 1000 nucleotides long (claims 36-38), and nucleic acids obtained from amplification (claims 8-14) encompass mutants variants and homologs, as well as sequences from other species, that have not been taught or described by the specification. All of the claims referenced herein recite language that is sufficiently "open" such that the claims encompass unspecified sequences on either side of the recited SEQ ID NOS. Such nucleic acids therefore encompass a large genus of sequences that have not been disclosed or described by the specification. The single sequence of Accession number AP002562 does not represent a significant portion of the claimed genus of mutants, variants, homologs, and sequences from other species, encompassed by the broad claim recitation. For example, SEQ ID NO: 5 is found completely within Genbank accession number AE015280 which is directed to a strain of Shigella

flexneri ([gi:24053029]: Shigella flexneri 2a str. 301 section 243 of 412 of the complete genome). The alignment is provided below:

Query (SEQ ID NO: 5): 1 aatacataacagaaacctgaaacacaa 27

Sbjct (Shigella flexneri 2a str.301) : 9155 aatacataacagaaacctgaaacacaa 9129

It is noted that SEQ ID NOS: 1-4 and 6-8 also are found completely within the genome for this strain of Shigella either in accession number AE015280 or AE 015281. This region of the shigella genome, however, is not completely complementary to the E.coli genome, therefore sequences containing unspecified sequences on either side of the indicated SEQ ID NOS or amplified by the recited primers (with regard to claims 8-14) encompass sequences from shigella flexneri, for example, that have not been taught or described in the specification. It is noted that claims 8-14 recite "obtained from amplification of an E. coli nucleic acid", however this recitation is not limited to sequences from E. coli because it is well known in the art that E. coli can be, and is, transformed to expresses sequences from other species. Further, with regard to claims 8-14, it is also well known in the art that PCR can result in non specific amplification such that the claims broadly encompass amplification of mutants, variants, and homologs of the recited sequences, as well as sequences from other species.

It is noted that claim 8 has been amended to recite "and the nucleic acid contains E. coli open reading frame Ecs3459". This recitation, however, does not limit the genus of encompassed nucleic acids because it is unclear if the term "the nucleic acid" refers to the claimed nucleic acid obtained from amplification, or the nucleic acid template in line 2 of claim 8. Further, regardless of such, the term "ECs3459" is an arbitrary delineation as the specification does not specifically define the sequences encompassed by such recitation. The specification, at

page 3, states that the region between 81889-83238 of Genbank Accession number AP002562, contains 3 open reading frames, ECs3458, ECs3459, and ECs3460, which encode hypothetical proteins with unknown functions. However, the specification does not teach what the actual sequence of ECs3459 is, or where it starts and stops with Genbank Accession number AP002562. Further, even if the specification did set forth a specific sequence, the recitation would still encompass any homologs or variants of the open reading frames, ECs3458 and ECs3460 from any source, thus encompassing unknown, uncharacterized open reading frames. As stated previously, it is well known in the art that E. coli can be, and is, transformed to express sequences from other species, therefore, while a sequence amplified by two primers can include sequences from E. coli, it can also include sequences from other species.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the recited SEQ ID NOS, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes

v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Response to Arguments

7. It is noted that upon further consideration, the written description rejection has been withdrawn for claims 1-3 and 5-6. These claims recite primer sequences with an upper length limit of up to 40 nucleotides. As such, these sequences are not likely to encompass whole open reading frames. As such, the rejection was not applied to newly added claim 39. If applicants wish to resubmit canceled claim 18, applicant may do so. Further, as the specific sequences of SEQ ID NOS 1-8 have been taught, they represent a significant portion of the claimed nucleic acids, and are thus deemed to represent the sequences encompassed by the claims. The amendment to claim 1, to recite that they are used to generate a nucleic acid containing E. coli

open reading frame ECs3459, does not limit the encompassed sequences because the specification has not taught what the sequence of ECs3459 is.

The response traverses the rejection with regard to claim 8 and the claims dependent from such. The response asserts that the claims have been amended to point out that the claimed nucleic acid contains E coli open reading frame ECs3459. This argument has been thoroughly reviewed but was not found persuasive because, as stated previously, the specification has not taught what the sequence of ECs3459 is. Additionally, even if the specification had taught the specific sequence of ECs3459, the 'detailed chemical structure of the encompassed polynucleotides' as asserted by the response would not limit the genus of claimed nucleic acids to exclude unknown, uncharacterized variants and homologs of ECs3458 and ECs3460, from any source. The assertion that the nucleic acid of claim 8 does not encompass sequences from shigella flexneri is not found persuasive, because depending on the conditions used for amplification, non specific amplification can occur, including amplification of sequences from other species.

For these reasons and the reasons made of record above, the rejection is maintained for claims 8-14 and newly applied to claims 36-38.

Indefinite

8. Claims 1-15, 23-26 and newly added claims 36-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite primers that contain a specific SEQ ID NO (SEQ ID NO: 1-4): but the claims also recite that the primer can be a minimum of 18 nucleotides in length. The term "containing" stipulates that the full sequence is present in the larger sequence, however SEQ ID NOS: 3 and 4 are each 24 nucleotides in length. Consequently, it is unclear how a sequence can "contain" either SEQ ID NO: 3 or 4 and be 18 nucleotides long. Further, the claims recite probes that contain a specific SEQ ID NO: (SEQ ID NOS: 5-8) but also recite that the probe can be a minimum of 26 nucleotides. The term "containing" stipulates that the full sequence is present in the larger sequence, however SEQ ID NOS5-7 are each 27 nucleotides in length. Consequently, it is unclear how a sequence can "contain" either SEQ ID NO: 5, 6, or 7 and be 26 nucleotides long.

Response to Arguments

9. The response traverses the rejection. The response asserts that those skilled in the art would clearly understand that a) primers containing SEQ ID NOS 1 and 2 are at least 18 nucleotides in length, and b) primers containing SEQ ID NOS 3 and 4 are at least 24 nucleotides in length, but then contradicts itself in stating "in other words, 18 nucleotides are the minimal length of the primers containing SEQ ID NOS 1, 2, 3, or 4". A similarly confusing explanation is set forth for the probes of SEQ ID NOS 5-8. As such, given the recitation in the claims and the indefiniteness as set forth above, and the arguments in the response, it is unclear whether the claims are meant to set forth sequences that comprise the sequences of SEQ ID NOS 1, 2, 3, 4, up to 40 nucleotides in length, or whether they are meant to encompass parts of them with unspecified sequences on either side.

10. Newly amended claim 8 lack sufficient antecedent basis for the recitation of "the nucleic acid", because it is unclear if the term "the nucleic acid" refers to the claimed nucleic acid obtained from amplification, or the nucleic acid template in line 2 of claim 8.

Maintained Rejections

Claim Rejections - 35 USC § 102

11. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Accession number AF175847 (November 2000).

Accession number AF175847 teaches a sequence that contains a sequence complementary to SEQ ID NO: 5 as shown below. The sequence of accession number is 161 nucleotides long. It is noted that the recitation of "sequences complementary thereto" has been broadly interpreted to encompass sequences complementary to portions of SEQ ID NO: 5, as the recitation does not limit the claim to sequences that contain the complete complement of SEQ ID NO: 5.

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Qy          7 TAACAGAAACCTGAAACA 24
              ||||||||||||||||||
Db         24 TAACAGAAACCTGAAACA 7
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12. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Accession number AX002476 (March 2000).

Accession number AX002476 teaches a sequence that contains a sequence complementary to SEQ ID NO: 6 as shown below. The sequence of accession number is 20

nucleotides long. It is noted that the recitation of "sequences complementary thereto" has been broadly interpreted to encompass sequences complementary to portions of SEQ ID NO: 6, as the recitation does not limit the claim to sequences that contain the complete complement of SEQ ID NO: 6.

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Qy          11 TTCCTGCGATTTC 23
               |||||||||||||
Db          17 TTCCTGCGATTTC 5
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Response to Arguments

13. The response asserts that claim 15 has been amended to limit the claimed group nucleic acid to a group consisting of SEQ ID NOS 5-8 "and their complements". This argument has been thoroughly reviewed but was not found persuasive. The recitation of "sequences complementary thereto", given it's broadest reasonable interpretation, encompasses sequences complementary to portions of the recited SEQ ID NOs, as the recitation does not limit the claim to sequences that contain the complete complement of the recited SEQ ID NOs.

Claim Rejections - 35 USC § 103

14. Claims 1-3, 5-6, 8-15 and newly added claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genbank Accession number AE005490 (first appeared in Genbank on 1/25/2003), Genbank Accession number AE000346 (December 1, 2000), Genbank accession number Z70523 (April 1996) and Genbank accession number D90887 (1997) in view of Buck et al (Referred to as Buck: Biotechniques, vol. 27, pp 528-536, 1999), Hammond et al (Referred to

as Hammond; US Patent 5,374,718), Hogan (US Patent 5,693,469) and Tijhie et al (Referred to as Tijhie; J. Microbiol. Meth. Vol. 18, pp 137-150, 1993).

Accession number AE005490 teaches a gene sequence from the E. coli genome at positions. The accession number specifically teaches that the encoded proteins for genes from positions 1933-3282 are 100% identical to E. coli K 12. Accession numbers AE000346 (December 1, 2000), Z70523 (April 1996) and D90887 also teach sequences from different strains of E. coli. The positions of each of SEQ ID NOS 1-8 within these accession numbers are provided. The accession numbers do not teach the sequences of SEQ ID NOS 1-8, however, Hammond teaches and exemplifies a method for picking probes for detection of a particular organism (in the case of Hammond it was for Chlamydia pneumoniae) that are species specific (see abstract). Hammond teaches that probes are chosen upon alignment of different sequences of a particular region and that genus specific and species specific probes can be chosen based on the alignment of the sequences to target regions of similarity or differences (see col. 2, lines 49-60, and cols 4-8). Hogan teaches targeting sequences within the E. coli genome for detection of E. coli. Tijhie teaches a method of picking probes and primers for genus and species detection of Chlamydia. Tijhie teaches using computer assisted sequences analysis of known sequences to identify regions of similarity and differences to construct genus and species specific probes and primers (see abstract, fig. 1, pages 141-142). Buck teaches design strategies for choosing DNA primers. Buck expressly provides evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all

possible 18 mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that *every single primer* worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, *every single control primer* functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95 control primers functioned, which represent 1/3 of all possible primers in the target region. This clearly shows that every primer would have a reasonable expectation of success.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to construct probes and primers for the purpose of detecting E. coli. The ordinary artisan would have been motivated to do so given the teachings of Hogan that nucleic acid based methods could be used to detect E. coli. Given that a large number of E. coli genomic sequences containing SEQ ID NOS 1-8 were known (see Accession numbers cited above) the ordinary artisan would have been motivated to use such sequences to detect E. coli in view of the large amount of teaching in the prior art as to how to pick probes and primers for the detection of a target organism when target sequences were known (see Hammond, Hogan, Tijhie, and Buck). The claims encompass a genus of nucleic acid sequences which the ordinary artisan would have been motivated to construct for the purpose of detecting E. coli. Given the known E. coli sequences and the large amount of direction given in the prior art, the ordinary artisan would

have been motivated to construct a genus of primers and probes for detection of E. coli. The ordinary artisan would have been motivated to target this particular region of E coli because Accession Number AE005490 teaches that this region is conserved in E. coli. Further, given the teachings of Hammond and Tijhie, the ordinary artisan would also have observed that this region of E. coli was conserved upon aligning the available genomic sequences of E. coli and would have been motivated to target this conserved region for the purpose of constructing probes and primers to detect E. coli. The genus of probes and primers that the skilled artisan would be motivated to construct given the teachings of the prior art are considered equivalent for the purpose of detecting E. coli to the genus of claimed probes and primers, absent secondary consideration. The claims encompass a fairly large genus and the ordinary artisan would have motivated to generate a genus of equivalent probes and primers for the purpose of detecting E.coli, therefore the genus of sequences encompassed by the claims obvious over the cited art. The state of the art was very high at the time the invention was filed with regard to picking primers and probes from already known sequences for the purpose of detecting the sequences as exemplified by the teachings of Buck, Hogan, Hammond, and Tijhie.

It is noted that the instant rejection has not been applied to claims 4, 7, and 19-26. As exemplified by the specification, such specific sequences exhibited unexpected results in that they were capable of detecting E. coli and not a large number of other genus and species of bacteria, including certain strains of Shigella, which is known in the art to be closely related to E. coli. As such, claims directed to the scope of the unexpected results (that is the specific SEQ ID NOS) are allowable over the cited prior art. However, the remaining claims are broader in scope and are not directed to any specific sequence, but rather to a large genus of sequences. (Further,

addition of sequences on either side of SEQ ID NOS 1-8 would be expected to change the hybridization specificity of the resulting sequences as compared to those exemplified by the specification.) Since an extremely large amount of prior art was available at the time the invention was filed with regard to picking probes and primers to already known sequences (the larger sequence from which the genus of sequences containing or comprising the recited SEQ ID NOS was known) for the purposes of detecting those sequences, the genus of sequences encompassed by the claims is obvious over the teachings of the prior art. While picking the *specific* sequences of nucleic acid molecules consisting of any one of SEQ ID NOS 1-8 is not obvious as the prior art does not lead the ordinary artisan to pick the specific sequences consisting of SEQ ID NOS: 1-8, the claims are not directed to specific sequences but to a large genus of sequences which the prior art does provide motivation to construct for the purposes of detecting the large sequence from which the genus is derived. Further, the teachings of the prior art provide a reasonable expectation of success that such genus of sequences will be able to be used as probes and primers for detection of certain strains of E. coli.

Response to Arguments

15. The response traverses the rejection on the grounds that Buck describes a method using purified sequences which would eliminate any potential non specific annealing of the primers to contaminating sequences whereas the nucleic acids of claim 1 can be used to amplify and detect unpurified E coli sequences from samples. The response further asserts that it is unreasonable to extrapolate data obtained on an artificial and purified sequence to a natural and unpurified

sequence. These arguments have been thoroughly reviewed but were found unpersuasive. While Buck teaches a method using purified sequences, there is nothing in the teaching of Buck, or any scientific reasoning in the prior art in general, that would suggest that primers from a known sequence couldn't be reasonably expected to amplify the known sequence flanked by the primers. The response provides no scientific reasoning as to why one would not expect the primers of Buck to work if other contaminating sequences were also present. Admittedly, some non specific amplification could occur, however, this does not mean that the primers wouldn't be able to amplify the sequence they were targeted to amplify. The response's assertion that the sequences of claim 1 could be used to amplify 'natural' and 'unpurified' sequences provides no reason as to why such primers are different from any primer that was picked from an already known sequence, to amplify the target flanked by the primers, regardless of what other sequences might be present in the sample. Given that PCR technology has been known, practiced, and optimized in the art for more than a decade before the instant invention was filed, the responses' assertion that Buck teaching cannot be used in the instant situation is not found persuasive.

Furthermore, it is noted that the specification provides no teaching of the specific criteria for picking primers that can be used to amplify 'natural' and 'unpurified' sequences, vs: "artificial" and "purified" sequences, nor does the specification demonstrate using or generating any sequences for amplification other than SEQ ID NOS 1-4, whereas the claims encompass sequences larger than such. In fact, the specification teaches picking SEQ ID NOS: 1-4 from a Genbank accession number, which could be construed as "artificial" and "purified" (see page 3). Since the specification has not taught any other primers, the specification lacks a teaching to direct the artisan to pick any primers other than SEQ ID NO: 1-4 to amplify "natural' and

'unpurified' sequences. If the responses' assertion were taken to its conclusion, it appears that the response is suggesting that sequences other than the specific sequences of SEQ ID NO 1-4 would not necessarily be able to amplify 'natural' and 'unpurified' sequences. If the response means to assert that SEQ ID NOS 1-4, are able to distinguish E. coli from other bacteria present in a sample, it is noted that the MPEP states that the scope of the unexpected results must be commensurate in scope with the claimed invention:

716.02(d) [R-2] Unexpected Results Commensurate in Scope With Claimed Invention
Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support."

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Claims 4, 7, 23-26 and newly added claims 40-43 are free of the cited prior art.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton
Primary Examiner
Art Unit 1634
8/26/04